

## REMARKS

The Office Action dated January 7, 2008 has been carefully considered. Before proceeding to a more detailed discussion of the rejections of all of the claims in this application on the basis of Kuslich Publication No. 2002/0077701 in view of one or more other references, it is believed appropriate to first point out that the present application is a divisional of Application Serial No. 09/947,785 filed September 6, 2001 (now U.S. Patent No. 6,736,815). This divisional status is confirmed in the filing receipt dated May 10, 2004 in the present application. This priority date is of substantial significance because the Kuslich published application upon which all of the rejections are based has a filing date of December 17, 2001, which is subsequent to the filing date of Applicant's parent application, but Kuslich does claim priority based on Provisional Application Serial No. 60/256,014, filed on December 15, 2000.

Thus, disclosure which appears in the provisional application of Kuslich would have an effective date prior to Applicant's effective date, but new matter added to the non-provisional application of Kuslich filed on December 17, 2001, would not be prior art with regard to the present application. A copy of Provisional Application Serial No. 60/256,014 filed by Kuslich on December 15, 2000 is attached hereto as Exhibit A. The disclosure of this provisional application is **not** co-extensive with the published application upon which the Examiner relies. Rather, the common subject matter of the provisional and non-provisional applications comprises only paragraphs 1-122 of the published application and only figures 1-23. Thus, paragraphs 123-133 and figures 24-30 of Published Application Serial No. 2002/0077701 are **new matter** and **not prior art** as to the present application.

As a result, the provisional application discloses only methods and apparatus for treating the **interior** of a spinal disc whereas the present invention is directed to treating the **exterior** of a spinal disc. Furthermore, in paragraph 7 on page 7 of the outstanding Office Action, which is captioned "Response to Arguments", the Examiner makes specific reference to figure 28 of Kuslich, which is not prior art, as support for his position. Since this portion of Kuslich is unavailable as prior art, the Examiner's response to applicant's arguments does not have any basis in the record.

Furthermore, the present claims have been amended to recite that they are directed to an apparatus for treating “the exterior of” a ruptured disc and that the elongate member recited in the claims is “adapted to pull said band around the exterior of a spinal disc.” Thus, the claims, as amended, leave no doubt that they are directed to an apparatus for treating the exterior of a spinal disc not, as in the prior art portion of the Kuslich nonprovisional application, to treatment of the interior of a spinal disc.

Still further, Applicant cannot agree with the characterization of Jepson type claims made by the Examiner at page 7 of the outstanding Office Action. Rather, as stated in Rowe v. Dror, 112 F.3d 473, 479 (Fed. Cir. 1997), the Jepson form allows an applicant to use the preamble to recite “elements or steps of the claimed invention which are conventional or known”, 37 C.F.R. 1.75(e). When this form is employed, the claim preamble defines not only the context of the claimed invention but also its scope. As stated in MPEP, 608.01(m), the Jepson form of claim “is to be considered a combination claim” and “the preamble of this form of claim is considered to positively and clearly include all the elements or steps recited therein as a part of the claimed combination.”

Thus, just as the recitation “balloon angioplasty catheter” in Rowe v. Dror, patentably distinguished from a prior art reference drawn to a balloon catheter for delivering medication, so here does the recited improvement deal with an apparatus for treating the exterior of a spinal disc patentably distinguished from the Kuslich apparatus for treating the interior of a spinal disc.

Turning now to the specific rejections, claims 1-8 and 10-13 have been rejected as unpatentable over Kuslich in view of Wedeen Patent No. 4,606,335. In making this rejection, the Examiner has relied upon figure 28 of the Kuslich published application, which figure is not prior art. The Wedeen patent does nothing to remedy the deficiencies of the prior art portion of the Kuslich application. There is absolutely no need for any type of deployment device to assist in deployment of the Kuslich device to be placed in the interior of a spinal disc and attempting to combine the wire passer of Wedeen with the interior spinal device of Kuslich would make absolutely no sense. Stated differently, it would be readily apparent to those skilled in the art that the devices of Kuslich, designed for an interior lining in a spinal structure, and the wire passer of Wedeen,

designed to pass over wire around the outside of a bone, have absolutely nothing in common and that it would not make any sense to attempt to combine them.

In addition, for the reasons stated in Applicant's filed October 24, 2007, at pages 7 and 8, dependent claims 2-8 and 10-13 are also patentably distinct from the combination of Kuslich and Wedeen for separate and independent reasons. Those reasons are incorporated by reference herein.

Claims 21 and 22 have been rejected as unpatentable over Kuslich in view of Wedeen and Mikhail Patent No. 5,308,349. This rejection is subject to the same deficiencies as the rejection made on the basis of Kuslich and Wedeen discussed above. In addition, the device of Mikhail which is a retractor device designed for use in posterior cruciate ligament surgery in which it is used to position and protect the ligament, has nothing to do with the internal spinal disc lining devices of Kuslich or with the wire passer of Wedeen. The attempted reconstruction of claims 21 and 22 from these 3 totally unrelated references is manifestly improper. Indeed, the fact that the Examiner has found it necessary to go so far afield in attempting to find disclosures of bits and pieces of the subject matter recited in claims 21 and 22 is a strong indication of the impropriety of this rejection.

Claims 1-8, 10-13 and 23-27 have been rejected as unpatentable over Kuslich in view of Kaladelfos Patent No. 6,494,887. Once again, this rejection must fail because of the Examiner's reliance upon the non-prior art portion of Kuslich including figure 28. In addition, it is respectfully pointed out that Kaladelfos is directed to a suturing device which is nothing more than a hollow curved needle through which a suture may be passed. This reference cannot be properly combined with the Kuslich reference any more than Wedeen or Mikhail could be. There is absolutely no need for a suturing device with regard to the deployment of the interior spinal disc lining of Kuslich and the Examiner suggests no reason why there might be. One skilled in the art would view the use of a surgical needle to be utterly inappropriate with regard to the interior band of Kuslich which is intended to be "inserted into a cavity formed in a degenerating disc" as set forth in paragraph 60 of Kuslich. The use of the needle of Kaladelfos would also be dangerous if an attempt were made to use it in the interior of a spinal disc for the same reasons that the use of the wire passer of Wedeen would also be dangerous.

Furthermore, the dependent claims are independently patentably distinct from this combination of references for the same reasons as those set forth with regard to the combination of Kuslich and Wedeen.

With regard to claim 27, which recites "a pair of opposite-hand guide members", it is not true that these guide members constitute a mere duplication of the essential working parts of a device. Rather, these opposite-hand guide members are cooperating elements and, as shown in figure 5 of the present application, cannot be considered a mere duplication of the essential working parts of a device. Furthermore, there is nothing in the prior art which shows the combination of the elongate member, the band and the guide members. It is believed appropriate to ask the Examiner to seriously reconsider the rejection of claim 27 and to withdraw it.

In summary, none of the rejections of record can stand because they are all based on the non-prior art portion of Kuslich. In addition, the attempted combinations of Kuslich with the other references are fundamentally improper because the remaining references are directed to subject matter entirely different and distinct from that of Kuslich.

It is believed that all of the claims in this application are allowable and a favorable action is respectfully solicited.

The Commissioner is authorized to charge any additional fees required by the filing of these papers, and to credit any overpayment to Orrick Herrington & Sutcliffe's Deposit Account No. **150665**.

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Respectfully submitted,

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